

REMARKS

In the Office Action dated April 9, 2009, the Examiner rejected claims 1, 3, 5-7, 20, 21, 24, and 25 under 35 U.S.C. § 103(a) as being unpatentable over European Patent Document EP 0568045 A1 to Kawata et al. ("*Kawata*"); rejected claims 1, 3-7, 20, 21, 24, and 25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,935,141 to Buck et al. ("*Buck*") in view of *Kawata*; and rejected claim 4 under U.S.C. § 103(a) as being unpatentable over *Kawata* in view of *Buck* and U.S. Patent No. 5,707,522 to Maeda et al. ("*Maeda*").

Claims 1, 3-21, and 24-27 are currently pending in this application. Claims 8-19, 26, and 27 were previously withdrawn. No new matter is presented by this Reply.

Applicant respectfully traverses the Examiner's rejection of claims 1, 3, 5-7, 20, 21, 24, and 25 under 35 U.S.C. § 103(a) as being unpatentable over *Kawata*. Applicant submits that the Examiner has failed to establish a case of prima facie obviousness at least because *Kawata* does not teach or suggest every element of the rejected claims as amended. Furthermore, the claims comprise features with unexpected or non-obvious properties. Specifically, as stated in the M.P.E.P., "[e]vidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness." M.P.E.P. 716.02(a)(II).

In the Office Action the Examiner argues that "Kawata teaches that the pore size and number of pores can result from different process conditions and this teaching is noted as a teaching that one of ordinary skill in the art could change the pore size and the number of pores if so desired." (Office Action at 12.) The Examiner further states that "it would have been obvious to obtain the desired density based on Kawata that

teaches one can change the size and number of pores present on the surface of the membrane.” (Office Action at 13.) Applicant respectfully disagrees.

Kawata discloses a process whereby “many micropores of relatively large pore diameters in their outer surface layer can be readily obtained.” (Page 7, lines 17-18.) In other words, *Kawata* only discloses modification of pore diameter to a larger size.

Kawata does not, however, in any way disclose or suggest modification of the number of pores or the number of pores per unit area. The Examiner contends that “a density property would be inherent to the structural limitation of a number of pores present on the surface combined with a known pore size.” (Office Action at 12-13.) The feature of “10,000 to 150,000 pores per mm^2 ,” as recited in amended independent claim 1, is a **number of pores in a given unit of area** (i.e., number of pores / mm^2). The size of the pores in a given area can decrease or increase while the number of pores per unit area remains exactly the same. Accordingly, modifying the size of the pores does not imply a modification of the number of pores, let alone a specific density range of “10,000 to 150,000 pores per mm^2 ,” as recited in amended independent claim 1.

The Examiner has failed to establish a case of prima facie obviousness with respect to independent claim 1 at least because *Kawata* does not disclose or suggest “a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm , the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 .”

Additionally, Applicant refers the Examiner to the Examples described in paragraphs [0043]-[0055] of Applicant’s published specification. In accordance with Applicant’s claims, Example 1 and Example 2 include a fourth outer layer in the form of

a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm , the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 . Specifically, Example 1 includes 62,500 pores in the range of 0.5 to 3 μm per mm^2 (see ¶ [0046]), and Example 2 includes 18,700 pores in the range of 0.5 to 3 μm per mm^2 (see ¶ [0048]). Example 3, which serves as a comparison with Examples 1 and 2, includes 3,650 pores in the range of 0.5 to 3 μm per mm^2 (i.e., not within Applicant's claimed range). (See ¶ [0051].) As noted in the Table, the percentage of scrapped fiber bundles resulting from the parameters used in Examples 1 and 2 was 0.1% and 6%, respectively. The percentage of scrapped fiber bundles resulting from the parameters used in Example 3, however, increased markedly to 48%.

In other words, the comparative example using hollow fibers that included a number of pores per unit area of the claimed size only slightly outside of the claimed range resulted in substantially increased production scrap, which is undesirable. The importance of the number of pores per unit area within the claimed range is neither taught nor suggested by *Kawata*. Further, one of skill in the art at the time of the present invention would not have reasonably expected the parameters recited in independent claim 1 to successfully reduce production scrap in this manner. Moreover, none of the cited prior art references teach or disclose these important properties recited in independent claim 1. Accordingly, the feature of "a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm , the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 ," as recited in independent claim 1, includes

unexpected or non-obvious properties, which rebut any prima facie case of obviousness established by the Examiner.

For at least the aforementioned reasons, amended independent claim 1 is allowable over *Kawata* and the § 103(a) rejection of independent claim 1 should be withdrawn and the claim allowed. Furthermore, dependent claims 3, 5-7, 20, 21, 24, and 25 are allowable at least due to their dependence from amended independent claim 1 and due to their additional recitations of patentable subject matter.

Applicant also respectfully traverses and requests the withdrawal of the rejection of claim 1, 3-7, 20, 21, 24, and 25 under 35 U.S.C. § 103(a) as being unpatentable over *Buck* in view of *Kawata*. Applicant respectfully requests that the Examiner withdraw this rejection at least because *Buck* and *Kawata* do not disclose or suggest each element of the claims.

Buck discloses selectively permeable asymmetric membranes. (Abstract.) The membranes are “produced from hydrophobic and hydrophilic polymers . . . [with] a three-layered structure including a first dense thin skin layer which includes uniform pores of a size whereby proteins having a molecular weight of at least that of albumin are substantially rejected therefrom, an intermediate second layer in the form of a sponge and having a higher diffusive permeability than the first layer, and a third layer with a finger-like structure which provides mechanical stability. These membranes are preferably formed in the shape of hollow fibers, with the first layer as the inner layer thereof.” (Abstract.)

Buck does not teach, suggest, or disclose “a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm ”

as recited in amended independent claim 1. When referring to “a pore size that is 0.5 to 3.0 micron, the Examiner concedes that “Buck differs and does not teach this limitation.” (Office Action at 8.) However, the Examiner contends that “Buck teaches embodiments where the pore size increases from the inner layer to the outer layer and Buck teaches the same pore size of the inner layer as found in Applicant’s disclosure in the specification.” (Office Action at 14.)

Applicant submits that the Office Action is incorrect as a factual matter. *Buck* discloses that:

[t]he substantially uniform pores in this skin layer are typically in the range of between about 20 and 200 Angstroms, preferably between about 20 and 80 Angstroms, i.e., most preferably of about 80 Angstroms, and this layer determines the sieving and permeability properties of the membrane.

(Col. 4, lines 11-15.) When converted, *Buck* discloses pore sizes between 2-20 nanometers, preferably between 2 and 8 nanometers, and most preferably at 8 nanometers. Applicant’s published specification discloses that:

[p]ore size can be made in different ranges, e.g. for a low flux membrane in the range of 5-10 nm, and for a high flux membrane between 5 and 20 nm, preferably 7 to 12.

(Specification at ¶ [0027].) Therefore, although the ranges disclosed in *Buck* and Applicant’s specification overlap in places, the ranges are clearly not the same. Even assuming, *arguendo*, that the ranges were exactly the same, which Applicant does not concede, having similar pore sizes for one layer in no way teaches or suggests that the same pores sizes are used in all layers. Furthermore, as noted in Applicant’s previous Reply, *Buck* does not even disclose a fourth layer, let alone the features thereof. For at

least these reasons, *Buck* does not disclose or suggest a “fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm ,” as recited in amended independent claim 1. Moreover, *Kawata* does not remedy the deficiencies of *Buck*.

Further, *Buck* fails to disclose or suggest “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 ,” as recited in amended independent claim 1. The Examiner contends that “[i]t further would have been obvious to produce an outer sponge layer with the property of pore density in the range of 10,000 to 150,000 pores per mm^2 .” (Office Action at 7.) The Examiner also contends that “Applicant’s limitation of the pore density of 10,000 to 150,000 pores per mm^2 is rejected over *Buck* as being inherent to the structure and obvious over *Buck*.” (Office Action at 13.) The Examiner has failed to provide any further analysis or discussion of this issue with respect to *Buck* in the Office Action.

Accordingly, Applicant respectfully submits that the Examiner has not met the required burden for establishing a prima facie case of obviousness. For example, “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” M.P.E.P. 2142. Additionally, “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result

from a given set of circumstances is not sufficient.” M.P.E.P. 2112(IV), (emphasis added).

The Office Action does not reference any disclosure in *Buck*, or provide any analysis or evidence as to why *Buck* necessarily discloses that “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²” or why this would have been obvious.

Accordingly, the Office Action’s conclusory statements that “[i]t . . . would have been obvious to produce an outer sponge layer with the property of pore density in the range of 10,000 to 150,000 pores per mm²,” and that “the pore density of 10,000 to 150,000 pores per mm² is rejected over Buck as being inherent to the structure and obvious over Buck” are not sufficient to establish a prima facie case of obviousness.

Further, as noted above, *Buck* does not disclose a fourth layer, let alone “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²,” as recited in amended independent claim 1.

Also, as noted above and described in Applicant’s examples, hollow fibers that included a number of pores per unit area of the claimed size only slightly outside of the claimed range resulted in substantially increased production scrap. The importance of the number of pores per unit area within the claimed range is neither taught nor suggested by *Buck*. Moreover, as discussed above, *Kawata* does not remedy the above-mentioned deficiencies of *Buck*.

Thus, for at least the aforementioned reasons, amended independent claim 1 is allowable over the cited references, and the § 103 rejection of amended independent claim 1 should be withdrawn. Further, the claims 3-7, 20, 21, 24, and 25 are also

allowable due at least to their dependence from amended independent claim 1 and due to their additional recitations of patentable subject matter. Applicant respectfully asks that the rejection of these dependent claims be withdrawn as well.

Applicant respectfully traverses the Examiner's rejection of claim 4 under 35 U.S.C. § 103(a) as being unpatentable over *Kawata* in view of *Buck* and *Maeda*. *Maeda* discloses "a permselective membrane of the polyacrylonitrile copolymer of the kind as described above which is an asymmetric membrane having, as the outermost layer, a dense layer (skin layer) having a thickness of 0.05 to 5 μm and substantially free from pores having a pore size of at least 0.5 μm ." (Col. 3, lines 19-24.)

Maeda, however, at the very least, does not disclose or suggest "the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 ," as recited in amended independent claim 1. For at least this reason, claim 4, which depends from amended independent claim 1, is allowable over the cited references. Thus, Applicant respectfully asks that the Examiner withdraw the § 103 rejection of claim 4 and allow the claim.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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